# Senate Committee on Environment and Public Works Hearing Entitled, "Toxic Substances Control Act Amendments Implementation." June 22, 2022

Questions for the Record for The Honorable Michal Freedhoff Ph.D.

## **Chairman Carper:**

- 1. I was pleased to learn of EPA's strong actions to better account for risks to workers in your assessments under TSCA, and to ensure that your rules afford them the protections they deserve. But I've also heard some criticisms that EPA has gone too far, and that your approach is duplicative of Occupational Safety and Health Administration (OSHA) regulations already on the books.
  - a. Would you help us to better understand what you and your staff are doing to address risks to workers exposed to chemicals, and how that aligns with EPA's responsibilities under TSCA

#### **RESPONSE:**

TSCA requires EPA to consider risks to relevant "potentially exposed or susceptible subpopulations" when we do risk evaluations – and workers are clearly an example of a subpopulation that may be identified as "potentially exposed or susceptible." Consistent with that mandate, we've been looking at - and identifying unreasonable risks to - workers in individual TSCA risk evaluations. TSCA also requires EPA to address the unreasonable risks it identifies in risk evaluations through the risk management process.

EPA and OSHA meet regularly and are closely coordinating efforts to ensure protections for workers are both consistent and practical. Because OSHA rules don't apply to self-employed or State and local public-sector workers that aren't covered by State OSHA plans and because many of OSHA's chemical-specific rules are decades old and do not reflect current science (and even OSHA has acknowledged that these are "outdated and inadequate for ensuring protection of worker health" – see <a href="https://www.osha.gov/annotated-pels">https://www.osha.gov/annotated-pels</a>), EPA cannot just assume that all workers will be properly covered by OSHA rules and move on. Moreover, as EPA considers risk management options for worker protection, EPA seeks to select options that provide a high level of confidence that there will not be unreasonable risks. EPA is also cognizant that respiratory and eye and face protection safety violations are almost always on OSHA's annual top 10 list of most frequent safety violations (see <a href="https://www.osha.gov/top10citedstandards">https://www.osha.gov/top10citedstandards</a>) and EPA factors this into decisions about how to best protect workers.

The Agency also knows, however, that many companies comply with and even in some cases go beyond what OSHA requires to protect workers. When TSCA risk management rules include requirements to protect workers, EPA expects to strive for consistency with OSHA rules and industry best practices whenever possible, leveling the playing field for all companies, and will ensure that all workers are protected against unreasonable risk no matter where they live or who employs them.

- 2. This question goes to the issue of what is "good" science. Perhaps a good example is your decision to consider risks of a chemical broadly rather than consider so-called "conditions of use" when you assess the risk of a chemical. As I understand it, "conditions of use" refers to the processes or protections that companies might use to minimize releases and exposures to the chemical. I believe you would assert that the decision to consider risk broadly is the scientifically sound way to proceed. I understand the industry feels good science dictates that you consider "conditions of use" in these risk evaluations.
  - a. Would you help us understand this disagreement over how science should be used to assess chemical risk?

## **RESPONSE:**

Science is the backbone of everything we do at EPA, and I'm firmly committed to strong science and scientific integrity to support an effective and sustainable TSCA program. The issue you describe, however, is not about science, but rather risk communication.

To clarify, EPA has considered and will continue to consider the "conditions of use" of a chemical in all of its risk evaluations, as the law requires. TSCA defines "conditions of use" as the circumstances "under which a chemical substance is intended, known, or reasonably foreseen to be manufactured, processed, distributed in commerce, used, or disposed of." TSCA section 6 further requires EPA to conduct risk evaluations "to determine whether a chemical substance presents an unreasonable risk of injury to health or the environment, without consideration of costs or other non-risk factors, including an unreasonable risk to a potentially exposed or susceptible subpopulation identified as relevant to the risk evaluation by the Administrator, under the conditions of use." (emphasis added).

The previous Administration made several policy decisions that are important to understand. First, they excluded consideration of certain exposure pathways for certain chemicals (e.g., exposure to the general population from breathing or drinking contaminated air or water) and interpreted the statute to allow Agency discretion to effectively narrow the scope of TSCA risk evaluations. Second, they decided to make risk determinations on each individual condition of use separately instead of considering the entirety of the risks posed by the "chemical substance."

We are now including the previously-excluded exposure pathways in our risk evaluations to ensure that those assessments are comprehensive and will not leave potential risks on the table – something that our scientific peer reviewers have consistently supported and encouraged. And secondly, we have started to revise some of our risk determinations to reflect a risk determination on the "chemical substance" as a whole under TSCA section 6(b), as opposed to each individual "condition of use" in isolation.

This approach to making risk determinations does not mean that all uses of a chemical are dangerous. For many chemicals, there are risky uses, less risky uses and perhaps even some uses that are not risky at all. We will clearly identify conditions of use that drive the unreasonable risk, and conditions of use that do not drive the unreasonable risk, in our "whole chemical" risk determinations. Our goal is to be as clear as possible on which uses of the chemical are driving

the unreasonable risk determination for the chemical substance, and thus where we'd expect to focus efforts in the TSCA Section 6(a) risk management rulemaking to eliminate the unreasonable risk presented by the chemical substance. The ultimate message the Agency wants to be able to send to the public is that we've done a comprehensive TSCA risk evaluation, managed unreasonable risk, that people can have confidence in our work, and that they can rest a little more easily at night knowing that they are now protected.

- 3. Recently, EPA took the important step of requesting that its Science Advisory Board provide advice on incorporating "cumulative impact" assessments into decision making to account for the fact that people and communities often experience multiple chemical and non-chemical stressors impacting their health, well-being, and quality of life. For example, exposure to multiple phthalates would be considered together to reflect the best science and actual exposures, and considering cumulative impacts would mean people that are exposed to phthalates and have limited financial resources, access to education, health care, etc.
  - a. What are OCSPP's plans for considering cumulative impacts in upcoming risk evaluations?

## **RESPONSE:**

There are multiple definitions of the term "cumulative risk assessment." The definition in EPA's 2003 Framework for Cumulative Risk Assessment (U.S. EPA, 2003) is "an analysis, characterization, and possible quantification of the combined risks to health and/or the environment from multiple agents and/or stressors." This could include the evaluation of multiple chemicals that jointly exert a toxic effect. EPA's Office of Research and Development also just finalized a report with regarding recommendations for advancing the Agency's cumulative impact research going forward.

TSCA does not explicitly require EPA to conduct cumulative risk assessments. However, when conducting risk evaluations, TSCA does require EPA to consider all reasonably available information and to ensure that risk determinations are based on the weight of scientific evidence and best available science. TSCA also gives EPA the authority under TSCA section 26(c) to take "any action authorized" under any provision of TSCA, in accordance with that provision, with respect to a category of chemical substances or mixtures. The definition of "category" is broad and may include substances that share similar structure, or physical, chemical, or biological properties. Where appropriate, EPA might use this authority to assess and consider the combined risk from multiple chemical substances (e.g., when there is an interrelated group of chemicals or mixtures). In some instances, the best available science may indicate that conducting a cumulative risk assessment is appropriate to ensure that risk to human health and the environment is adequately characterized.

EPA's Office of Pollution Prevention and Toxics (OPPT) is currently working to develop some proposed principles for cumulative risk assessment under TSCA. Once ready, we plan to seek scientific peer review (e.g., from the Science Advisory Committee on Chemicals (SACC)) and

solicit public comment, and to potentially incorporate feedback into a more detailed framework for conducting cumulative risk assessment under TSCA.

b. How does EPA intend to address cumulative risks in the new chemicals program, particularly to fence line communities, workers and other potentially exposed or susceptible subpopulations?

#### **RESPONSE**:

TSCA explicitly requires EPA to consider risks to "potentially exposed or susceptible subpopulations" in carrying out its new chemical reviews under TSCA section 5 – including risks to subpopulations like workers or fenceline communities – and we expect to continue and enhance our considerations in this area. With respect to exposures from multiple chemicals or non-chemical stressors, such considerations can help EPA to identify "potentially exposed or susceptible subpopulations" that may have increased vulnerabilities. However, the Agency's determination on risks under TSCA section–5 - and any risk management action taken in response - are focused on risks from the new chemical substance itself. OCSPP is working collaboratively with other offices at EPA to ensure the new chemicals program is utilizing the best available science in its reviews and that approaches are appropriately aligned across the Agency.

- 4. When Congress amended TSCA in 2016, it granted EPA new authority to gather the information it needs to conduct risk evaluations, including the authority to issue chemical testing orders. I am pleased to see this administration begin to use that authority, but significant data gaps remain for many of the chemicals that are currently undergoing risk evaluation.
  - a. Does EPA plan to issue additional testing orders for chemicals that are undergoing risk evaluation?

## **RESPONSE:**

EPA has issued 18 test orders for chemical substances undergoing risk evaluation. The Agency does not, at this time, anticipate issuing additional test orders for chemicals currently designated as high-priority substances because such orders would be unlikely to generate data in time for use in the forthcoming risk evaluations. However, moving forward, the Agency is actively working to ensure we collect data – including through use of our TSCA section 4 test order authority – sufficiently early in t process to support our prioritization, risk evaluation, and risk management efforts.

b. Does EPA plan to issue testing orders for mixtures, or combinations of chemicals that people are exposed to, including combinations of chemicals that are found in the same consumer product or released in the same community?

#### **RESPONSE:**

TSCA section 4 provides authority for EPA to require testing on mixtures when "the effects which the mixture's manufacture, distribution in commerce, processing, use, or disposal or any combination of such activities may have on health or the environment may not be reasonably and more efficiently determined or predicted by testing the chemical substances which comprise the mixture."15 U.S.C. § 2603(a)(1)(B).

EPA described its expectations with respect to testing of PFAS mixtures in response to a citizen's petition under TSCA section 21. That response (and the discussion on mixture testing at Unit III. B) is available on EPA's website: <a href="https://www.epa.gov/system/files/documents/2021-12/pfaspetitionresponse.pdf">https://www.epa.gov/system/files/documents/2021-12/pfaspetitionresponse.pdf</a>. EPA does not have expectations to require mixture testing for any of the chemicals undergoing TSCA risk evaluation at this time.

c. Chemical manufacturers have pushed back on the few orders that EPA has issued. What is EPA's response to industry opposition?

## **RESPONSE:**

The ability for EPA to issue testing requirements by order was new in the 2016 amendments. Because the previous administration didn't exercise this authority in a significant way, we are now – in many ways – still building the policies, processes and infrastructure of the test order process. Developing section 4 test orders is a complex and resource-intensive process involving many scientific and regulatory considerations. The new authority is an important tool in EPA's toolbox to be able to support TSCA risk evaluations and to get the information it needs, especially in light of the aggressive deadlines in the law. The staff working on this are actively working to identify ways to make the process go more smoothly. EPA has developed a document to help external stakeholders better understand the Agency's process for developing, drafting, and issuing section 4 test orders, available here:

https://www.epa.gov/system/files/documents/2022-03/issuing-a-section-4-order-24-march-2022.pdf. In addition, EPA published its policy with respect to identifying manufacturers subject to test orders here: <a href="https://www.epa.gov/system/files/documents/2022-08/Policy\_Manufacturing\_Processing\_August\_2022.pdf">https://www.epa.gov/system/files/documents/2022-08/Policy\_Manufacturing\_Processing\_August\_2022.pdf</a>

## **Senator Merkley:**

1. Dr. Freedhoff, I recently introduced the Alan Reinstein Ban Asbestos Now Act of 2022, which would ban eight recognized asbestos fibers. The TSCA Part 1 proposed rule for asbestos is focused on only one fiber – chrysotile– and only six specific conditions of use.

What is the basis for these limitations? Do you agree that it would be better for public health if all fibers and all conditions of use were banned?

## **RESPONSE:**

Under the previous Administration, EPA narrowed the scope of the TSCA risk evaluation for asbestos by only reviewing certain uses of one fiber type of this chemical, chrysotile asbestos. In 2019, a court ruled that the agency unlawfully excluded "legacy uses" and "associated disposal" from consideration as "conditions of use" under the TSCA Risk Evaluation Rule, resulting in the need to expand the agency's review of asbestos. In response to this court decision, EPA chose to finalize part one of its risk evaluation of asbestos and then turn to part two to address the legacy uses. Interested stakeholders challenged the agency's failure in part one to consider the risks of other asbestos fibers, conditions of use, health effects, and pathways of exposure, and EPA entered a settlement agreement to consider these issues in part two. The draft scope for part two of the risk evaluation was released in <a href="December 2021">December 2021</a> and includes legacy uses and associated disposal, other types of asbestos fibers in addition to chrysotile, and the use of asbestos in talc and talc-containing products. EPA will publish the final risk evaluation by December 1, 2024, and proceed with additional risk management action to address any unreasonable risks identified.

2. EPA's Part 1 proposed risk management rule for asbestos includes a two-year phase-out date for asbestos use in chlor-alkali production. My bill reflects this timeline. However, at my recent subcommittee hearing on the bill, I heard from stakeholders that this might not be feasible. Can you elaborate on why it may or may not be feasible for the chlor-alkali industry to transition from asbestos diaphragms in two years?

## **RESPONSE:**

The comment period for EPA's proposed risk management rule ended on July 13, 2022, and the Agency has received more than 150 comments. Comments are publicly available in the online rulemaking docket here: <a href="https://www.regulations.gov/docket/EPA-HQ-OPPT-2021-0057/document?documentTypes=Proposed%20Rule">https://www.regulations.gov/docket/EPA-HQ-OPPT-2021-0057/document?documentTypes=Proposed%20Rule</a>. A number of stakeholders have provided comments regarding the implications of a 2-year phase-out for use of asbestos in chlor-alkali production. Some have argued that chlorine is essential to disinfecting drinking water and the production of various other goods, and that EPA's proposed timeline for phase-out of asbestos in the chlor-alkali industry will have significant negative implications for public health and the economy. EPA is continuing to carefully review these and other comments and expects to provide a formal response to comments as part of the rulemaking process.

- 3. The Fiscal Year 2023 budget request seeks a 66% increase in funding for EPA's Toxics Risk Review and Prevention Program. As you know well, this program is responsible for protecting Americans from dangerous chemicals like asbestos through its authorities under the Toxic Substances Control Act, as amended by the bipartisan 2016 Lautenberg Act.
  - Given the expanded responsibilities that Congress tasked EPA with in the 2016 Lautenberg amendments, we all expected the agency would need more resources to get the job done. The vision for this program was always that 25% of agency costs would be covered through services fees, but the previous administration grossly undercounted the resources needed for this program. Dr. Freedhoff, the administration has taken an

important step in re-evaluating the TSCA Service Fees Rule, which sets industry fees authorized under TSCA.

a. How will a new fee approach help ensure that industry contributes its fair share of the costs of this program?

#### **RESPONSE:**

Ensuring the Agency had enough money to implement the law was a key principle of TSCA reform that everyone supported, and it is correct that Congress also told EPA to collect up to 25% of certain TSCA costs from fees. But the first fees rule didn't become effective until fiscal year 2019, and the cost baseline for setting those fees was based on the costs of implementing the 1976 law – not the 2016 amended version of the law that provided the Agency with substantially increased requirements and responsibilities.

The costs of the first ten risk evaluations – the most expensive actions that could have been subject to the first TSCA fees rule - were also completely excluded from being subject to fees in that rule. As a result, the Agency did not come close to collecting 25% of even that artificially low costs baseline; instead it was around 13%.

The law requires us to update the rule every three years, and our supplemental fees will soon be released for public comment. Consistent with Congress' direction in the FY22 appropriations bill to "properly consider full costs...in line with the Lautenberg Act's intent," EPA expects the updated fees rule would provide the Agency with 25% of the full costs of implementing relevant provisions of the new law. See Joint Explanatory Statement: <a href="https://docs.house.gov/billsthisweek/20220307/BILLS-117RCP35-JES-DIVISION-G.pdf">https://docs.house.gov/billsthisweek/20220307/BILLS-117RCP35-JES-DIVISION-G.pdf</a>. Ensuring sufficient funding is something that all stakeholders supported, including industry,

when the 2016 amendments were enacted – and that's also exactly what Congress told EPA to do

b. What are the consequences for families and communities from underfunding this program?

#### **RESPONSE:**

in the last Appropriations bill.

The promise of TSCA reform was to deliver to the American people long-overdue protections against dangerous chemicals. The additional resources requested in the President's 2023 Budget Request, together with establishing and collecting fees that reflect the actual estimated cost of EPA's TSCA work, are critical to ensuring the success of the TSCA program and keeping families and communities safe. But fundamentally, it is in everyone's interests, including industry's, that EPA has the resources and other processes in place that will allow it to be able to make credible determinations on chemical risks and provide regulatory certainty to the public and stakeholders in accordance with our statutory deadlines.

## **Ranking Member Capito:**

1. You mentioned in your testimony that there are only two health assessors working within the TSCA program. Please provide an accounting of the number of full-time employees currently working within the TSCA program, organized by job title, area of expertise, and program office.

#### **RESPONSE:**

To clarify, as indicated in EPA's testimony, there were only two health assessors currently in the New Chemicals Division at the time of the June 2022 hearing. "Human health assessor" is not an EPA job series or title, but was intended to generally refer to staff scientists with background and expertise in and current responsibilities for human health risk assessments in the new chemicals program. In addition to the two permanent health assessors, since the hearing, EPA has temporarily moved some existing employees with the appropriate technical and scientific training from their current positions into the New Chemicals Division to help address the current shortage of human health risk assessors. EPA has now successfully filled temporary (i.e., "detail") positions for a total of seven employees currently working to perform human health risk assessments for the next 3-4 months.

The New Chemicals Division has been allocated additional FTE following the March, 2022 enactment of the last Appropriations bill, and some of these new recruits have started to be onboarded (pending the completion of applicable background check and other requirements). We anticipate that by Spring 2023, we will hopefully have 11 human health assessors on board.

The employee accounting (Enclosure A) is organized by division and branch within the Office of Pollution Prevention and Toxics.

2. What role do health assessors have in chemical reviews under the TSCA program?

## **RESPONSE:**

Under TSCA, EPA is required to review and make an affirmative determination on the safety of new chemicals before they can enter the market. EPA uses an integrated approach that draws on knowledge and experience across disciplinary and organizational lines to conduct new chemical reviews. EPA conducts a full life-cycle risk assessment of the substance, including chemistry, engineering, environmental releases, environmental fate, exposure (workers, general population, consumers and environment) and hazard (human and ecological) assessments, and then integrates those components into a risk assessment to inform the determination of whether the chemical poses or may pose an unreasonable risk to human health or the environment under the conditions of use. Human health assessors play an integral role in the assessment of human health hazards and risks as part of this process.

3. Do the health assessors do other work that could be addressed by other Agency employees?

#### **RESPONSE:**

The two health assessors referred to at the hearing in OPPT's new chemicals division are already devoting 100% of their time to carrying out new chemical reviews (including both premanufacturing notice and low volume exemption reviews). They are not performing other tasks that could be given to other employees to take on.

4. How many health assessors were working under the TSCA program during 2016?

#### **RESPONSE:**

The TSCA program with EPA's Office of Pollution Prevention and Toxics (OPPT) underwent a substantial reorganization in 2020. As part of that process, the human health assessors within the "Risk Assessment Division," which previously provided assessment to support both the new chemicals and existing chemicals assessments were assigned to one of two new divisions. Human health assessors that went to the New Chemicals Division conduct risk assessments to support the New Chemicals Program and those that went to the "Existing Chemicals Risk Assessment Division" conduct risk assessments to support the Existing Chemicals Program. In 2016, the "Risk Assessment Division" had approximately 17 employees with expertise in human health risk assessments supporting both new and existing chemical programs in OPPT. In 2020, following the reorganization of OCSPP, of 289 total employees in OPPT, 28 employees had responsibility for conducting TSCA human health risk assessment activities, including eight focusing on new chemical risk assessments, 19 on existing chemical risk evaluations, and one on cross-cutting issues.

5. What is the average tenure of a health assessor working under the TSCA program?

## **RESPONSE:**

EPA has not analyzed personnel records to generate an average tenure of a health assessor working under the TSCA program. However, we have observed high levels of employee turnover across the office in recent years following the TSCA amendments.

6. Why do you think the Agency is having a difficult time retaining these types of employees and please identify any changes you are considering to ensure a sufficient number of health assessors are employed within the TSCA program?

#### **RESPONSE:**

The role of a health assessor in the TSCA new chemicals program is a challenging one. Congress gave EPA a relatively short window of time to review submissions and assess risks from new chemicals. This is no small task, as the program receives hundreds of submissions each year. But on top of that, the program has been historically underfunded. The new chemicals

program is currently operating with less than 50% of the resources it needs to carry out the program. As a result, career staff have been working in a very high-stress environment for a very long time.

Every year, the federal government conducts an Employee Viewpoint Survey to assess staff morale and other aspects of their jobs. Across the board, OCSPP's 2021 scores show improvement from 2020, and in most instances, the scores are at their highest levels ever. That being said, the data highlight areas for significant improvement even though we have made some meaningful progress in the past year. For example, there is a continued sentiment expressed that the workload in OCSPP is not reasonable – which is, of course, true, given the resource challenges we've been facing for the past 6 years with new TSCA.

7. Do you agree that there are enough resources already allotted to the TSCA program to hire more than two full-time health assessors without additional appropriations?

## **RESPONSE:**

Before the enactment of the FY 22 appropriations, EPA had the authority to hire additional human health assessors. However, the broader TSCA program has been consistently underfunded since the 2016 amendments. As such, the Agency still currently lacks the resources with which to implement the program as Congress intended and has struggled to allocate these resources to address competing statutory responsibilities and deadlines for both new and existing chemicals.

The FY 2022 appropriations, which was passed in March 2022, provided some additional resources. There are currently 25 hiring actions underway across the Office, including seven in the New Chemicals Division. However, the hiring process takes time. Positions must be advertised, qualified candidates must be identified, panels are customarily convened to conduct interviews, selections must be made, offers must be formalized, conveyed and accepted, and security background checks must be completed – all before a new employee can be onboarded to begin orientation and training. In addition to the two permanent human health assessors, we now have five human health assessors onboarded on temporary assignments for the next 3-4 months for a total of seven employees working to perform human health risk assessments. We anticipate having a total of nine human health assessors with a mixture of permanent and temporary details by end of the year, and, by Spring 2023, we will hopefully have 11 full time permanent human health assessors.

Even under the FY2022 appropriations, EPA still estimates that we have less than 50% of the resources we need to carry out the program as Congress intended. The President's Budget Request for FY2023 requests an increase of \$64 million and 201 additional full-time employees to support the TSCA program. Those additional resources, together with establishing and collecting fees that reflect the full cost of EPA's TSCA work are critical to ensuring the success of the TSCA program.

8. I appreciate your commitment made during the hearing to utilize a tiered approach to classifying and prioritizing OCSPP's plans to address PFAS chemicals. I understand that that your Office is already in the process of establishing this tiered approach. Can you please elaborate further on how this process is being undertaken and some of the main challenges this effort has faced thus far?

## **RESPONSE:**

In June 2022, the Agency issued the first in a series of test orders under TSCA to require companies to conduct and submit testing on PFAS. The order employs a tiered screening and testing process, as TSCA requires, under which the results of screening-level tests or assessments of available information inform the decision as to whether one or more additional tests are necessary. The results of all the first-tier testing are required to be submitted to EPA within 400 days of the effective date of the order and will inform the decision as to whether additional tests are necessary. This effort is part of our National PFAS Testing Strategy to help identify PFAS data needs and require testing to fill those gaps, which was announced in 2021 in tandem with EPA's Strategic Roadmap to confront PFAS contamination nationwide.

Not all PFAS are the same, and EPA expects that different PFAS will present differing levels of concern. For example, a PFAS that does not dissolve in water would not be expected to pose a risk of exposures from drinking water. And some PFAS have been shown to cause health effects at much lower concentrations than others. Given that there are thousands of chemicals that are considered PFAS, EPA recognizes that assessing PFAS one at a time will make it impossible to understand or address the risks these substances may pose to human health and the environment.

Building off Congress' direction in the 2020 National Defense Authorization Act (NDAA) to develop a process for prioritizing which PFAS or categories of PFAS should be subject to additional research efforts based on potential for human exposure to, toxicity of, and other available information, the National PFAS Testing Strategy employs a category-based approach. Specifically, using published scientific methods, EPA assigned 6,504 PFAS into smaller categories based on similarities in structure and physical-chemical properties. Of these categories, EPA identified 24 that lack toxicity data to inform EPA's understanding of the potential human health effects and contain PFAS with at least one identifiable manufacturer to whom EPA could issue a test order. Rather than seeking data about each of the thousands of individual PFAS, which would require extensive resources in terms of time, costs, and animals, the Strategy aims to prioritize categories that are data-poor when it comes to the potential health effects for earlier action, and to identify a single representative substance(s) for each chemical category where categories have been constructed to span the landscape of PFAS of interest. More details on the National PFAS Testing Strategy are available on EPA's website: https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/national-pfas-testingstrategy.

9. In order to manage the EPA's workload, as well as to facilitate more effective risk communication, does the EPA intend to use a more easily understandable approach to

classifying the varying hazard profiles of PFAS substances, for example by assigning labels such as "high-concern," "low-concern," or "no-concern"?

#### **RESPONSE:**

The purpose of the National PFAS Testing Strategy is to identify and fill gaps in the Agency's understanding of thousands of PFAS chemicals, most of which have limited or no toxicity data. This information could further inform the Agency's future research, monitoring, and regulatory efforts on PFAS. EPA recognizes that not all PFAS are the same, and that some PFAS will likely present differing levels of concern than others. EPA does not expect to assign each PFAS a label such as "high-concern", "low-concern," etc. as part of this effort at this time. For many PFAS, the data do not exist to do so, which is the significant gap the testing strategy aims to address. The Agency agrees that we cannot achieve our mission without effectively communicating with communities, individuals, businesses, the media, and Tribal, state, and local partners about the known and potential health risks associated with these chemicals. When EPA communicates risk, it is the Agency's goal to provide meaningful, understandable, and actionable information to many audiences.

10. The National Defense Authorization Act for Fiscal Year 2020 amended section 8(a) of TSCA to authorize the EPA to require reporting by manufacturers of the chemical substance the EPA has defined as PFAS:

"Not later than January 1, 2023, the Administrator shall promulgate a rule in accordance with this subsection requiring each person who has **manufactured a chemical substance that is a perfluoroalkyl or polyfluoroalkyl substance** in any year since January 1, 2011, to submit to the Administrator a report that includes, for each year since January, 2011, the information described in subparagraphs (A) through (G) of paragraph (2)." [emphasis added]

In the EPA's proposed rule implementing this NDAA provision, the preamble states:

"[A]rticles containing PFAS...are included in the scope of reportable chemical substances."

How do the Office's proposed regulations implementing section 8 of TSCA define "article" and "chemical substance"?

#### **RESPONSE:**

TSCA does not define "article," but EPA has defined "article" for purposes of Section 8(a) reporting rules in 40 CFR 704.3. The term "article" means:

"a manufactured item (1) which is formed to a specific shape or design during manufacture, (2) which has end use function(s) dependent in whole or in part upon its shape or design during end use, and (3) which has either no change of chemical composition during its end use or only those changes of composition which have no

commercial purpose separate from that of the article, and that result from a chemical reaction that occurs upon end use of other chemical substances, mixtures, or articles; except that fluids and particles are not considered articles regardless of shape or design."

The term "chemical substance" is defined in Section 3(2) of TSCA as follows:

- "(A) Except as provided in subparagraph (B), the term "chemical substance" means any organic or inorganic substance of a particular molecular identity, including—
  - (i) any combination of such substances occurring in whole or in part as a result of a chemical reaction or occurring in nature, and
  - (ii) any element or uncombined radical.
- (B) Such term does not include—
  - (i) any mixture,
  - (ii) any pesticide (as defined in the Federal Insecticide, Fungicide, and Rodenticide Act [7 U.S.C. 136 et seq.]) when manufactured, processed, or distributed in commerce for use as a pesticide,
  - (iii) tobacco or any tobacco product,
  - (iv) any source material, special nuclear material, or byproduct material (as such terms are defined in the Atomic Energy Act of 1954 [42 U.S.C. 2011 et seq.] and regulations issued under such Act),
  - (v) any article the sale of which is subject to the tax imposed by section 4181 of the Internal Revenue Code of 1986 [26 U.S.C. 4181] (determined without regard to any exemptions from such tax provided by section 4182 or 4221 or any other provision of such Code) and any component of such an article (limited to shot shells, cartridges, and components of shot shells and cartridges), and (vi) any food, food additive, drug, cosmetic, or device (as such terms are defined in section 201 of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 321]) when manufactured, processed, or distributed in commerce for use as a food, food additive, drug, cosmetic, or device.
- 11. Do these definitions establish a distinction between "article" and "chemical substance"?

#### **RESPONSE:**

A chemical substance can be part of an article.

12. Do you believe section 7351 of the 2020 NDAA authorizes the EPA to require reporting by manufacturers of articles containing PFAS? If so, how many entities does the EPA envision would be subject to these new reporting requirements?

#### **RESPONSE:**

The National Defense Authorization Act for Fiscal Year 2020 (Pub. L. 116-92, section 7351) amended TSCA section 8(a) in December 2019, adding section 8(a)(7), titled PFAS Data. TSCA section 8(a)(7) requires EPA to promulgate a rule "requiring each person who has manufactured

a chemical substance that is a [PFAS] in any year since January 1, 2011" to report information described in TSCA section 8(a)(2)(A) through (G). TSCA section 3(9) defines "manufacture" to include import of a chemical substance into the customs territory of the United States. Therefore, EPA proposed to apply the requirements in the TSCA 8(a)(7) reporting rule to those who import articles containing PFAS. EPA estimated 234 respondents would report under the one-time data call associated with the proposed rule. However, this number does not include the importers of articles containing PFAS, which EPA has sought more data on and is continuing to analyze. Following publication of the proposed rule, EPA convened a Small Business Advocacy Review (SBAR) Panel. We plan to publish the Initial Regulatory Flexibility Analysis and request comment and will carefully consider all feedback received during these processes as we work to finalize the rule.

13. The EPA itself recognized the difficulty in identifying the cost implications for importers of articles containing PFAS in its proposed section 8(a) rule. Does OCSPP still hold the view that it is difficult for importers of articles containing PFAS to have knowledge of the presence of a covered substance in a particular article? If so, what challenges does this pose to implementing the reporting requirements contained within the EPA's proposed section 8(a) rule?

#### **RESPONSE:**

EPA proposed that manufacturers (including importers) will report information to the extent that the information is known to or reasonably ascertainable by the manufacturer. The proposed rule at 40 CFR 705.3 would define "Known to or reasonably ascertainable by" to include "all information in a person's possession or control, plus all information that a reasonable person similarly situated might be expected to possess, control, or know." This reporting standard would require reporting entities to evaluate their current level of knowledge of their manufactured products (including imports), as well as evaluate whether there is additional information that a reasonable person, similarly situated, would be expected to know, possess, or control. This standard carries with it an exercise of due diligence. EPA acknowledged in the proposed rule that it is possible that an importer of articles containing PFAS may not have knowledge that they have imported PFAS. However, such entities – after they have conducted their due diligence – would not be required to report under the rule but should nonetheless document their activities to support any claims they might need to make related to due diligence.

As noted previously, following the proposed rule, EPA convened an SBAR Panel to hear directly from small entities on the anticipated impact of the proposed rule on their organizations, and to get feedback regarding recommended paths forward to finalize a rulemaking that would minimize the burden of compliance on small entities while still achieving the objectives of TSCA section 8(a)(7). EPA also heard from public commenters, including articles importers, regarding specific implementation concerns. EPA plans to publish the Initial Regulatory Flexibility Analysis and request comment and will carefully consider all feedback received during these processes as we work to finalize the rule.

14. Industry has indicated that manufacturers subject to the proposed section 8(a) reporting requirements are unlikely to have much of the required data for years prior to 2016. Obtaining these data will require significant financial resources and time. Is the EPA able to quantify the economic burden associated with the significant expansion in the scope of reporting requirements for manufacturers of PFAS substances? What will be the regulatory purpose of these data?

#### **RESPONSE:**

Congress, in the National Defense Authorization Act for Fiscal Year 2020 (Pub. L. No. 116-92 § 7351), specifically directed EPA to promulgate a rule "requiring each person who has manufactured a chemical substance that is a [PFAS] in any year since January 1, 2011" to report certain information to the Agency. The proposed rule is consistent with this charge. We plan to publish the Initial Regulatory Flexibility Analysis addressing this question and request comment. The Agency would benefit from collecting the requested information on PFAS-containing articles (including articles containing PFAS as part of surface coatings) because the information would improve the Agency's knowledge of various products which may contain PFAS, their categories of use, production volumes, and exposure data. Such data are not currently known to EPA.

15. Can the EPA feasibly regulate or conduct enforcement actions related to evaluating all articles containing PFAS? How would this expansive mission affect personnel and financial resources you testify are already scarce?

## **RESPONSE:**

As noted previously, following the proposed rule, EPA convened an SBAR Panel to hear directly from small entities on the anticipated impact of the proposed rule on their organizations, and to get feedback regarding recommended paths forward to finalize a rulemaking that would minimize the burden of compliance on small entities while still achieving the objectives of TSCA section 8(a)(7). EPA also heard from public commenters, including articles importers, regarding specific implementation concerns. EPA is considering all comments and information received as we work to finalize the rule.

16. In your response to my question during the hearing regarding OCSPP's modeling assumption that personal protective equipment (PPE) is not being worn by workers, you justified this decision based, in part, on the EPA's inability to confirm whether self-employed workers are adhering to the Occupational Safety and Health Administration's (OSHA) PPE requirements. Did Congress intend for TSCA to be a risk-based or hazard-based statute?

## **RESPONSE:**

The "unreasonable risk" standard for TSCA risk evaluations is purely risk-based. In amending TSCA in 2016, Congress told EPA to determine – through a TSCA risk evaluation – whether a

chemical presents an "unreasonable risk of injury to health or the environment, without consideration of costs or other nonrisk factors," including unreasonable risk to potentially exposed or susceptible subpopulations, which may include workers. 15 U.S.C. 2605(b)(4)(A).

17. What is the difference between hazard- and risk-based approaches for chemical evaluations?

## **RESPONSE:**

A hazard-based approach would consider only the chemical's hazards (i.e., potential adverse effects associated with exposure), whereas a risk-based approach looks at both hazard and exposure to determine risk (i.e., the chance of harmful effects to human health or to ecological systems resulting from exposure to an environmental stressor).

18. Please provide a justification as to how the "whole chemical" approach is an appropriate interpretation of a risk-based statute.

## **RESPONSE:**

The "whole chemical" approach, as applied in several recently revised risk determinations for some of the first 10 chemical risk evaluations under TSCA, is an approach that looks at both hazards and exposures from the chemical substance as a whole, as well as other risk-related factors, to determine whether that chemical substance presents an unreasonable risk under its conditions of use, consistent with the language in TSCA section 6(b)(4)(A). In revising the risk determinations, nothing has changed with respect to the underlying analysis or the risk-based manner in which those evaluations were carried out.

19. What is the risk-based standard that is being applied in the PPE example? If it is not risk-based, why not?

## **RESPONSE:**

As described in an announcement on June 30, 2021, EPA intends to remove the assumptions regarding the use of personal protective equipment (PPE) in making the unreasonable risk determinations under TSCA section 6. The risk-based standard under TSCA remains the same – the Agency is looking at the hazards from and exposures to a chemical to determine whether that chemical substance presents an unreasonable risk. The Agency is just no longer simply assuming that workers always appropriately wear PPE. OSHA rules don't apply to all employers. Many of OSHA's chemical-specific rules date back to the 1970s, and even OSHA has acknowledged that these are "outdated and inadequate for ensuring protection of worker health." See <a href="https://www.osha.gov/annotated-pels">https://www.osha.gov/annotated-pels</a>. And on top of that, respiratory and eye and face protection safety violations are almost always on OSHA's annual top 10 list of most frequent safety violations. See <a href="https://www.osha.gov/top10citedstandards">https://www.osha.gov/top10citedstandards</a>. That said, the Agency is also aware

that many companies comply with and even go beyond what OSHA requires. The Agency's upcoming risk management rules will level the playing field for all companies by striving for consistency with OSHA rules and industry best practices whenever possible and ensure that all workers are protected against unreasonable risk no matter where they live or who employs them.

20. Does the EPA's apparent justification that the safety of self-employed workers cannot be guaranteed through OSHA standards imply that the EPA will need to levy enforcement actions against self-employed workers? If so, how will the EPA ensure that self-employed workers are adhering to TSCA? What scale of personnel and funding would that enforcement require?

#### **RESPONSE:**

The point emphasized in testimony is that OSHA requirements do not necessarily protect all workers, and that, as a factual matter, the requirements do not even apply to self-employed workers or State and local public-sector workers not covered by state plans. There are currently no regulatory requirements under TSCA that apply specifically to self-employed workers; as indicated previously, EPA intends for its future risk management actions to be reasonable and appropriately tailored while also including requirements to the extent necessary to address the identified unreasonable risk, as required by TSCA section 6(a).

21. Does the EPA intend to send enforcement inspectors to individual homes based on their purchasing history of covered chemical substances?

#### **RESPONSE:**

There are currently no regulatory requirements under TSCA that apply specifically to self-employed workers, and there are no final risk management rules on the first 10 chemical substances that underwent TSCA risk evaluations. As indicated previously, EPA intends for its future risk management actions to be reasonable and appropriately tailored while also including requirements to the extent necessary to address the identified unreasonable risk, as required by TSCA section 6(a).

22. What existing chemicals indicated as "high-priority" for a risk evaluation under TSCA are available to the average self-employed worker?

#### **RESPONSE:**

While large-scale manufacturing settings are where industrial chemical activities are typically thought to occur, smaller commercial settings may use chemical substances that may be considered "industrial chemicals." Such commercial operations include, but are not limited to, machine shops, metal fabricators, auto-repair shops, furniture manufacturing, or construction. Activities that may use industrial chemicals may be done by small businesses, self-employed

individuals, or DIY consumers. Many of the first 10 chemicals subject to TSCA risk evaluations are readily available to the general public. For example, methylene chloride, perchloroethylene, and trichloroethylene could be found in local home improvement stores, in various cleaning products, and on shelves in craft stores. There are numerous examples of individuals – as either commercial contractors or consumers – who were exposed to these dangerous chemicals and suffered illness or death.

23. Please provide any quantitative data comparing the rate of exposure to a high-priority existing chemical for self-employed workers compared to workers employed in conventional manufacturing and industrial facilities with existing industrial hygiene requirements in place.

#### **RESPONSE:**

EPA does not have such data. Worker exposures to chemicals are assessed on a chemical-by-chemical basis, and EPA's risk evaluations characterize risk to workers both with and without use of PPE. Supporting data becomes part of the risk evaluation and/or is made available in the public docket for the risk evaluation.

24. Following the EPA's release of Phase 1 of the asbestos risk management proposal earlier this year, public water utilities raised significant concerns about the availability of chlorine if a two-year phasedown on imported asbestos is required.

According to the American Water Works Association and the Association of Metropolitan Water Agencies, the average cost for each ton of chlorine delivered to water systems has increased by over 160 percent over the last 18 months. Multiple large systems have experienced 300 to 600 percent increases in the unit cost of chlorine over an 18-month period, with one system paying \$7000 per ton of chlorine. Are you aware of the concerns from the public water utility sector on the already rising prices of chlorine?

# **RESPONSE**:

Yes. We have learned from several water systems that the cost of chlorine and derivative products (e.g., sodium hypochlorite, ferric chloride, polyaluminum chloride, etc.) has increased substantially, at percentages consistent with those reported by the American Water Works Association and Association of Metropolitan Water Agencies. Furthermore, we have heard directly from the suppliers that sell these products to water systems that the suppliers are incurring increases in the cost of these products, and that they will pass these increased costs on to their customers (including water systems).

25. Do you agree that higher prices paid for chlorine are ultimately borne by ratepayers?

#### **RESPONSE:**

Increased expenditures for chemical supplies ultimately will be borne by the communities serviced by the water systems. However, the rates for water services charged to customers may be controlled by a governing body (e.g., local governments, water boards, etc.), and the allowable rates are not always sufficient to cover operating costs, in which case a water system may borrow funds to cover these additional costs.

26. Given these concerns, is the EPA considering exempting chlor-alkali facilities for chlorine production serving public water utilities from the two-year phasedown?

#### **RESPONSE:**

I have personally met with a number of industry stakeholders who described some very practical implementation concerns, and I can assure you we will be taking their feedback and other public comments very seriously and will factor those in as the Agency moves to finalize the rule.

27. If not, what is the EPA going to do to address these issues, since chlorine and other disinfectants are critical elements in providing clean water as well as meeting the EPA's regulatory mandates on water systems?

#### **RESPONSE:**

EPA cares a great deal about protecting the integrity of the nation's drinking water supply, and we have no intention of creating unnecessary supply chain concerns where they can be avoided. As indicated previously, EPA is aware of concerns and is currently reviewing public comments to determine next steps for the rule.

28. The European Union provided 26 years for the phasedown of asbestos diaphragms in chlorine production. Canada provided an 11-year window. Why did the EPA only give facilities two years under its proposed risk management rule for chrysotile asbestos when other countries had vastly different phasedown timelines?

#### **RESPONSE:**

EPA consulted with several companies in the chlor-alkali industry and companies that process and use chrysotile asbestos-containing sheet gaskets in chemical production as part of developing the proposed rule. EPA noted in the proposed rule that it was possible that the required changes could take longer than expected to implement for some, and also considered a longer, 5-year phasedown as one of the regulatory option alternatives. Since then, the Agency has heard from a number of industry stakeholders regarding implementation concerns with the proposed phasedown period. EPA will be closely considering their feedback and other public comments as the Agency moves to finalize the rule.

29. Section 1441 of the Safe Drinking Water Act offers public water systems their only recourse in the event they are not able to access adequate supplies of disinfectants. If the asbestos rule were finalized and up to one-third of US chlorine capacity were affected, would the EPA expect to see an increase of applications from public water systems under section 1441?

#### **RESPONSE:**

In the case of a significant decrease in availability of chlorine and its derivatives, and if water systems are unable to secure these chemicals from other suppliers, EPA would expect to receive applications for a certification of need under the authorities of section 1441 of the Safe Drinking Water Act (SDWA 1441). This is based on experience during 2021 when there was a temporary decrease in production of chlorine due to equipment problems and extreme weather events. EPA received 28 applications for a certification of need under SDWA 1441 between June 2021 and April 2022, the majority of which dealt with chlorine or its derivative products. EPA was able to successfully resolve these supply issues by working directly with water systems and chemical suppliers. The Agency is keenly aware of the supply chain and other concerns raised by public commenters, and we will carefully consider that information as we finalize the rule.

30. How, and with what resources, would the EPA respond to these petitions meant to provide relief from a crisis that the Agency itself created?

## **RESPONSE:**

EPA's Office of Water and Office of Chemical Safety and Pollution Prevention continue to coordinate closely on any potential chlorine manufacturing supply chain issues. EPA has staff and resources to support responding to SDWA 1441 applications, though these resource levels are established based on historic utilization of SDWA 1441. EPA also has undertaken a robust array of actions to prepare the water sector to respond to chemical supply issues, including an Incident Action Checklist, a supply chain resilience guide, direct technical assistance to individual water systems, an online water treatment chemical suppliers and manufacturer locator tool, and workshops with the water, chemical and critical manufacturing sectors.

The Department of Commerce (DOC) also has an important role in this process as the entity that issues orders to suppliers. EPA does not have information to comment on the resources that DOC has available to support these activities.

31. Do you expect the EPA and the Department of Commerce to have the means to sufficiently provide decontamination chemicals to public water systems under section 1441 in the event of a nationwide chlorine shortage?

#### **RESPONSE:**

Under the authorities of section 1441 of the Safe Drinking Water Act, EPA can issue a certification of need, which authorizes the Department of Commerce (DOC) to issue compulsory orders to a supplier for water treatment chemicals that are otherwise not reasonably available to the water system applicant. SDWA 1441 requires each water system experiencing a shortage to submit its own application, and the orders issued by DOC are issued to specific suppliers on behalf of the specific applicant. Because the SDWA requires this one-by-one process, these authorities may not be the most efficient means of resolving a large-scale shortage that could result in a large number of applications exceeding EPA's current processing capabilities. Furthermore, these authorities are effective only to the extent that there is sufficient availability of water treatment chemicals to meet the needs of water systems.

32. How does the EPA intend to respond to petitions under section 1441 of the Safe Drinking Water Act?

### **RESPONSE:**

In 2021, EPA established a process to respond to and process applications submitted under section 1441 of the Safe Drinking Water Act and posted this information on our website. EPA would follow this established process for any new applications submitted and received.

33. Does the Agency currently have a chlorine stockpile for emergencies or some other mechanism to expand supply in the market rapidly?

#### **RESPONSE:**

No, the Agency does not keep a stockpile of chlorine. As described previously, if public water systems experience a shortage or supply chain issues for water treatment chemicals and other critical supplies, EPA first encourages those systems to work with their current suppliers or identify other potential suppliers in their region, consult their primacy agency or permitting authority, and to reach out to existing mutual aid networks for additional relief.

34. Do you agree that the chlorine market is characterized by both a captive market and a merchant market, and that the majority of chlorine supplied to public water systems comes through the merchant market?

#### **RESPONSE:**

Chloralkali facilities that produce chlorine for captive use generally lack the logistics infrastructure to move chlorine into the merchant market.

35. If this is the case, how does the EPA intend to address shortages in the merchant market for chlorine to respond to section 1441 petitions if the Agency cannot import or pull from the captive market to make up for shortages?

#### **RESPONSE:**

EPA would process SDWA 1441 applications using the procedure noted in the response to question 32. Additionally, EPA would provide direct technical assistance to water systems in need in an attempt to identify manufacturers or suppliers that may have chlorine that could be sold to water systems.

36. In a memo addressed to your staff, you reiterated your commitment to conducting a "robust exchange of scientific views, with differing scientific opinions." Given this commitment, how would you intend to address situations in which a comp[l]eted risk evaluation relies on exposure assumptions that, after the public comment period concludes, have been proven to be inaccurate by data adhering to TSCA's best available science criteria?

## **RESPONSE:**

I am committed to upholding and advancing the principles of scientific integrity throughout OCSPP's work. Healthy discussion of differing scientific opinions ultimately improves the quality of the science in OCSPP's work. Separately, the public comment periods associated with various stages of the TSCA process (e.g., prioritization candidate identification, proposed priority designation, draft risk evaluation scope, draft risk evaluation, etc.), along with scientific peer review, all provide important opportunities to hear from our stakeholders, academics, and the public, to hear feedback on our assumptions and analyses, and to receive additional relevant data that may be used to inform our decisions.

Because our TSCA risk evaluations are based on reasonably available information, it is important that stakeholders engage with EPA during this process and share relevant information that may impact the evaluation. Once a risk evaluation has been finalized and where unreasonable risk has been determined, the law directs the Agency to proceed to rulemaking to eliminate that risk under section 6(a). During the risk management phase, real world exposure and other information that is reasonably available to the Agency can continue to inform the regulatory decision-making. Where new information becomes available after the TSCA process is complete, EPA has the authority under TSCA to re-prioritize the chemical for evaluation.

37. After stating that you anticipate missing every single TSCA statutory deadline, why did you direct resources from the statutorily authorized TSCA program to non-statutory programs such as Safer Choice and IRIS?

#### **RESPONSE:**

The IRIS program is implemented by EPA's Office of Research and Development, is not part of the OCSPP or TSCA budget, and no such resource direction has occurred.

Congress specifically directed EPA to budget for Safer Choice in the FY2022 omnibus appropriation, stating: "the Committees support the Safer Choice program and direct that the program be funded and operated consistent with prior years." The Safer Choice Program has the support of a near-universal group of stakeholders [see Enclosure B - June 2021 letter.] The OCSPP reorganization implemented by the previous Administration eliminated the Safer Choice Branch. In April 2021, consistent with Congress' direction, EPA reestablished Safer Choice as a stand-alone branch within OPPT using existing resources already dedicated to Safer Choice work and did not divert any TSCA budget resources to the efforts. The branch currently has nine FTE.

38. Can you please clarify if it is the EPA's intention under the proposed chrysotile asbestos risk management rulemaking to require the removal and replacement of every existing asbestos gasket within two years?

## **RESPONSE:**

EPA proposed to prohibit the manufacturing, processing, distribution in commerce, and commercial use of asbestos-containing gaskets, including the commercial use of existing asbestos-containing gaskets. Under the proposed rule, this prohibition would take effect two years after the effective date of the final rule for sheet gaskets in chemical production, and 180 days after the effective date of the final rule for other gaskets. EPA did not, however, intend for this rule to force removal of significant numbers of asbestos gaskets before the end of their useful life. In fact, EPA recognizes that there could be unintended consequences of doing so in terms of increased exposures and risks during the removal and subsequent disposal. EPA is reviewing the feedback received during the public comment period from stakeholders on the proposed rule and will consider, based on that feedback, potential improvements to clarify, and amend as necessary, the scope of the rule's requirements.

39. Has the EPA noticed a reduction in new chemical submissions over the past six months even as economic activity has approached pre-pandemic levels? Why do you think this reduction in submissions is occurring?

#### **RESPONSE:**

The number of new chemical notices and applications that EPA receives for review is entirely dependent on industry submitters. There are months with higher numbers of submissions, and months with lower numbers. Because of this, a six-month period is not enough to draw accurate conclusions on trends, and EPA has not conducted a formal or detailed analysis of submission trends. That said, EPA has observed decline in the annual number of PMN submissions from FY 2016 – FY 2020. The greatest drop occurred in FY 2019, which generally corresponds to the effective date of the TSCA fees rule increasing the fees associated with new chemical submissions. In FY 2019, for the first time, EPA also began to receive more exemption

applications than pre-manufacture notices. Submission rates for exemption applications have continued this trend, now generally making up 50-60% of total submissions received each year. In FY 2021, EPA received an <u>increase</u> in the total number of submissions over FY 2020 numbers (i.e., 511 in FY 2021 as compared to 441 in FY 2020). And for FY 2022, the Agency again received slightly more submissions than in FY 2021 (i.e., 520 in FY 2022).

40. Does the EPA intend to continue to use a chronological approach to addressing the backlog of new chemical submissions? In other words, does the EPA intend to act on the earliest submissions before turning to ones received later? If this is not your intended approach, please explain why and what your approach will be.

#### **RESPONSE:**

The new chemicals program does not apply a purely first-in-first-out approach. Every new chemical submission is different, and some may take considerably more or less time to review than others. Moreover, the program has historically operated in an iterative fashion, working closely with submitters throughout the process, allowing companies to submit additional information that may be useful in refining the risk assessment, implementing industry requests to voluntarily suspend review periods when companies want/need more time to review or assemble information. In cases where EPA does receive amended submissions or new information during the review period, EPA may need to "re-run" all or parts of its risk analysis. Intake, review and inclusion of any new information takes time and will necessarily delay final completion of that particular case review. Where companies have amended their original submission – in some cases multiple times over a period of months or even years– EPA informs those companies that their submission will be added to the queue and may have to wait for EPA to complete risk assessments for other submissions. In other words, late amendments are sometimes added to the end of the line for review as they are received, not 'put to the front of the line' just because the assessment was originally submitted and/or previously initiated at an earlier date.

Additionally, EPA recently announced a broad outreach effort to describe and discuss with stakeholders how the Agency evaluates certain data provided for new chemicals submissions (e.g., engineering) and common issues that cause EPA to have to reconduct risk assessments ("rework") for these submissions. The goal of this effort is to reduce rework of initial risk assessments for new chemicals submissions that is caused by submitters supplementing incomplete initial new chemicals review submissions. Rework of assessments has resulted in significant delays in EPA's review of these chemicals and stretched already limited resources. Both EPA and stakeholders share an interest in reducing process inefficiencies while also ensuring a protective review of new chemical risks. More information on this effort is available on EPA's website: <a href="https://www.epa.gov/reviewing-new-chemicals-under-toxic-substances-control-act-tsca/tsca-new-chemical-engineering">https://www.epa.gov/reviewing-new-chemicals-under-toxic-substances-control-act-tsca/tsca-new-chemical-engineering</a>.

41. Do you believe that a draft IRIS assessment can be used to inform a TSCA chemical evaluation?

#### **RESPONSE:**

Yes. Risk assessment involves (1) hazard identification, (2) dose-response assessment, (3) exposure assessment, and (4) risk characterization, which integrate dose-response and exposure information. IRIS assessments only provide chronic hazard and dose-response information that are then used by other Agency programs, including OCSPP. TSCA risk evaluations are developed specifically to determine whether a chemical substance presents unreasonable risk and to include all four aspects of risk assessment. Information used to support an IRIS assessment—whether draft or final—is information that must be considered in developing a draft TSCA risk evaluation in light of the statutory and regulatory requirement to consider reasonably available information and to base decisions on the best available science. The TSCA risk evaluation process ensures that our analyses are made available for public comment and peer review as appropriate, based on the weight of the scientific evidence, and consistent with the best available science.

42. Would an IRIS assessment ever be used in place of a TSCA risk evaluation?

#### **RESPONSE:**

No. IRIS assessments are not risk assessments or risk evaluations. Risk assessment involves (1) hazard identification, (2) dose-response assessment, (3) exposure assessment, and (4) risk characterization, which integrate dose-response and exposure information. IRIS assessments only provide chronic hazard and dose-response information that are then used by other Agency programs, including OCSPP. TSCA risk evaluations are developed specifically to determine whether a chemical substance presents unreasonable risk and to include all four aspects of risk assessment. Under TSCA, we must look at, for example, the acute hazards to workers and consumers, the way people could be exposed to the chemical in the real world, and the potential for environmental risk – all components that are not part of IRIS assessments. As such, TSCA risk evaluations must consider and apply a broader suite of scientific information than that assessed under the IRIS program. Thus, IRIS assessments could inform a TSCA risk evaluation, but could not replace it.

43. Section 26(k)(5) of TSCA requires the EPA to issue guidance "to assist interested persons in developing and submitting draft risk evaluations which shall be considered by the Administrator." EPA first issued this guidance in June 2017.

Following the hearing, the EPA committed to a new approach with regards to TSCA's new chemicals program. That approach entails an improved effort by the EPA to conduct stakeholder outreach in order to better communicate the type of data the Agency expects to receive in a new chemical submission. With this in mind, does the EPA intend to update the section 26(k)(5) guidance in accordance with the Agency's new approach to stakeholder outreach within new chemicals program?

#### **RESPONSE:**

The guidance you are referring to under TSCA section 26(1)(5) is specifically guidance for developing and submitting a draft risk evaluation on an existing chemical. EPA does not conduct "risk evaluations" on new chemical substances under TSCA section 6(b). Rather, TSCA requires that EPA review and make an affirmative determination on all new chemical notices pursuant to TSCA section 5(a)(3), prior to those chemicals entering the market. EPA does not intend to update the section 26(1)(5) guidance at this time.

As noted previously, we have recently announced a broad outreach effort to describe and discuss with stakeholders how the Agency evaluates certain data (i.e., engineering) provided for new chemicals submissions and common issues that cause EPA to have to re-do risk assessments for these submissions. The goal of this effort is to reduce rework of initial risk assessments for new chemicals submissions, furthering shared goals of new chemical reviews that are both high quality and timely. More information is available here: <a href="https://www.epa.gov/reviewing-new-chemicals-under-toxic-substances-control-act-tsca/tsca-new-chemical-engineering">https://www.epa.gov/reviewing-new-chemicals-under-toxic-substances-control-act-tsca/tsca-new-chemical-engineering</a>.

In addition, EPA has separately published a document titled "Points to Consider When Preparing TSCA New Chemical Notifications" – available on EPA's website:

https://www.epa.gov/reviewing-new-chemicals-under-toxic-substances-control-act-tsca/points-consider-when-preparing-tsca. This document provides general guidance relating to new chemical notices; preparation of Pre-manufacture Notices, Significant New Use Notices, and Exemption notices; EPA scientific approaches; and best practices. Further guidance on how to prepare new chemical notices is also available on EPA's website:

https://www.epa.gov/reviewing-new-chemicals-under-toxic-substances-control-act-tsca/filing-pre-manufacture-notice-epa#avoid. EPA may consider updating or supplementing this document in the future to support its outreach and communication efforts in the new chemicals program.

44. If you intend to update this guidance required by section 26(k)(5), will you commit to working with industry to better communicate the type of data that should be submitted within an industry-conducted risk evaluation in order to facilitate more efficient reviews?

## **RESPONSE:**

As noted above, EPA is not planning to update the TSCA section 26(1)(5) guidance at this time. However, we are absolutely committed to doing a better job at communicating the type of data that would be most beneficial in completing both reviews in the New Chemicals Program and risk evaluations in the Existing Chemicals Program. To that end, EPA has launched an outreach effort to describe and discuss with stakeholders how the Agency evaluates certain data provided for new chemicals submissions and common issues that cause EPA to redo or "rework" risk assessments. We also published the analysis supporting identification of these common issues, which included review of 94 cases where companies provided additional engineering information during the new chemical review period, available here: https://www.epa.gov/system/files/documents/2022-

<u>07/TSCA%20New%20Chemical%20Engineering%20Initiative%2C%20Analysis%20Methodology</u>%20and%20Results.pdf.

The first in a series of webinars on this topic occurred on July 27, 2022, and drew close to 300 participants. A second webinar occurred on October 18, 2022 with over 500 participants, focusing on EPA's considerations in evaluating qualitative claims or quantitative data, especially when they deviate from model defaults such as those used in the Chemical Screening Tool for Exposures and Environmental Releases (ChemSTEER) and its considerations for evaluating information about sites not controlled by the submitter.

## **Senator Inhofe:**

1. Dr. Freedhoff, on June 15, 2022 the EPA announced revised interim drinking water health advisories for PFOA, PFOS, GenX chemicals and PFBS. The new health advisories for several of these chemicals are at near-zero levels that are, in certain circumstances, below detection. How does the EPA expect to measure contamination to the levels set forth in the health advisories and do tools exist that will enable detection at these new levels?

## **RESPONSE:**

Based on current methods, the interim health advisory levels for perfluorooctanoic acid (PFOA) and perfluorooctane sulfonate (PFOS) that EPA released on June 15, 2022, are below the level of both detection (determining whether or not a substance is present) and quantitation (the ability to reliably determine how much of a substance is present). This means that it is possible for PFOA or PFOS to be present in drinking water at levels that exceed health advisories even if testing indicates no level of these chemicals. Based on current methods, the final health advisory levels for GenX chemicals and PFBS are above both the detection and quantitation levels, and therefore can be reliably measured using specified analytical methods in appropriate laboratory settings. EPA continues to conduct research and monitor advances in testing technology, methods, and techniques that may improve our ability to measure PFAS at lower levels.

a. Did the Science Advisory Board review the interim health advisory values for PFAS before EPA issued them?

#### **RESPONSE:**

Consistent with EPA's mission and responsibility to protect public health, EPA issued interim health advisories for PFOA and PFOS to help inform the public of new scientific information on these chemicals' health effects.

EPA continues to conduct extensive evaluations of human epidemiological and experimental animal study data to support the development of a National Primary Drinking Water Regulation for PFOA and PFOS. In November 2021, EPA released draft updated health effects analyses for PFOA and PFOS; these analyses are undergoing Science Advisory Board (SAB) review. EPA

evaluated over 400 peer-reviewed studies published since 2016 and used new approaches, tools, and models to identify and evaluate the information. Based on the new data and draft analyses, the levels at which negative health effects could occur are much lower than previously understood when EPA issued the 2016 Health Advisories for PFOA and PFOS (70 ppt) – including near zero for certain health effects.

In light of this new information, including peer-reviewed scientific studies, EPA also announced in November 2021 that the agency would move quickly to update the 2016 Health Advisories for PFOA and PFOS to reflect the new science and draft EPA analyses. To deliver on this commitment, EPA issued interim updated health advisories based on the draft 2021 analyses that are undergoing review by the SAB. The interim health advisories replace the 2016 final health advisories for PFOA and PFOS. EPA is working hard to review and respond to the SAB's August 2022 final report as the agency moves forward to develop Maximum Contaminant Level Goals (MCLGs) to support the development of a National Primary Drinking Water Regulation for PFOA and PFOS. At that time, EPA may update or remove the interim health advisories for PFOA and PFOS based on the best available science. Because the available health effects data indicate a number of different adverse effects resulting from exposure to very low levels of PFOA or PFOS, the health-based water values (health advisories and MCLGs) are likely to remain below the detection limit.

b. If not, why didn't you wait for a review by the Agency's science experts?

#### **RESPONSE:**

See response to (a) above.

2. The EPA has committed to issuing maximum contaminant levels (MCLs) under the Safe Drinking Water Act for the above listed chemicals in the near future. Was what prompted the EPA to issue the new health advisories prior to the MCLs statutory or policy based?

#### **RESPONSE:**

Consistent with EPA's mission and responsibility to protect public health, EPA issued interim health advisories for PFOA and PFOS to help inform the public of new scientific information on these chemicals' health effects. The Safe Drinking Water Act (SDWA) authorizes EPA to issue health advisories for contaminants that are not subject to a National Primary Drinking Water Regulation (NPDWR) (42 U.S.C. §300g-1(b)(1)(F)).

A health advisory provides information on a contaminant that can cause negative human health effects and is known or anticipated to occur in drinking water. EPA's health advisories are non-enforceable and non-regulatory. They provide technical information to drinking water system operators, as well as federal, state, Tribal, and local officials, on the health effects, analytical methods, and treatment technologies associated with drinking water contaminants. This health effects information includes the concentrations of such drinking water contaminants (the health

advisory "levels" or "values") at which adverse health effects are not anticipated to occur over specific exposure durations, such as one-day, 10-days or a lifetime.

a. Do you expect those MCLs to be different from the interim health advisory levels?

## **RESPONSE:**

EPA is currently developing the proposed National Primary Drinking Water Regulations (NPDWRs) for PFAS. As part of an NPDWR, EPA establishes MCLGs, which are the level of a contaminant in drinking water below which there is no known or expected risk to health. MCLGs are health-based goals that allow for a margin of safety, and they are non-enforceable. Because the available health effects data indicate a number of different adverse effects resulting from exposure to very low levels of PFOA or PFOS, the health-based water values (health advisories and MCLGs) for these PFAS are likely to remain below our ability to monitor for and detect PFOA and PFOS in finished drinking water.

As part of the NPDWR, EPA will also set an enforceable limit in the form of an MCL or a Treatment Technique. An MCL is the highest level of a contaminant that is allowed in drinking water. MCLs are set as close to MCLGs as feasible using the best available treatment technology, considering feasibility, and taking cost into consideration. MCLs are enforceable standards. As EPA is currently in the deliberative process for developing NPDWRs, we cannot speculate on potential values for MCLs or treatment technique requirements at this time. Consistent with EPA's PFAS Strategic Roadmap, the Agency plans to release a proposed NPDWR by the end of 2022 for public comment.

b. Do you expect they will be higher or lower, and if so, why?

#### **RESPONSE:**

See response to 2(a) above.

3. The strong implication in the new health advisories is that drinking water is safe only at the proscribed levels. Does EPA expect water providers to bear the cost of abatement?

#### **RESPONSE:**

Health Advisories are informational and not enforceable. They do not require any action on the part of the water provider. However, for utilities and communities that choose to take action, EPA has announced \$1 billion in fiscal year 2022 grant funding through the Bipartisan Infrastructure Law Emerging Contaminants in Small or Disadvantaged Communities Grant Program. This is the first of \$5 billion in grant funding through the Bipartisan Infrastructure Law (BIL) that can be used to reduce PFAS in drinking water in underserved communities, and the

BIL provides a total of \$10 billion to address PFAS or other emerging contaminants in water. Communities can also use funding through the general and BIL supplemental State Revolving Funds, totaling over \$23 billion over the next 5 years, to address emerging contaminants in water. More information is available in EPA's March 2022 Bipartisan Infrastructure Law SRF Memorandum, available at <a href="https://www.epa.gov/dwsrf/bipartisan-infrastructure-law-srf-memorandum">https://www.epa.gov/dwsrf/bipartisan-infrastructure-law-srf-memorandum</a>.

- 4. The American Conference of Governmental Industrial Hygienists (ACGIH) Threshold Limit Values (TLVs) are considered by most Industrial Hygienists to be the "gold standard" for exposure guidelines. OSHA, in their Permissible Exposure Limit (PEL) Annotated Tables references ACGIH TLVs as one of the three alternative occupational exposure limits to their PELs.
  - a. Are you aware that the EPA proposed Existing Chemical Exposure Limits (ECELs) are significantly lower than the ACGIH TLVs? If so, why are the EPA's proposed ECELs so much lower than the established TLV's?

## **RESPONSE:**

Yes, we are aware that EPA's proposed ECELs are significantly lower than the TLVs developed by ACGIH. We appreciate the work done by ACGIH guiding industrial hygienists to contribute to the overall improvement in worker protection.

There are several reasons why ACGIH TLVs may differ from ECELs. Because many TLVs are several decades old, they may not fully capture either the complete database considered in risk evaluations or more recent advances in modeling and scientific interpretation of toxicological data. ECELs, which EPA considers to represent the best available science, are derived from information in the risk evaluation, which is the result of a rigorous systematic review process that includes an investigation of the entirety of the reasonably available current literature in order to identify all relevant adverse health effects. Additionally, by using the information from the risk evaluation, ECELs incorporate advanced modeling and peer-reviewed methodologies for determining exposure levels below which unreasonable risk to health would no longer be presented.

5. Pursuant to Section 6(b) of the OSH Act, OSHA must adhere to procedures and considerations in rulemaking, which includes technological and economic feasibility. Technological feasibility evaluates what is achievable using work practice or engineering controls that are commonly known and readily available. Economic feasibility evaluates whether the standard threatens the existence or the competitive stability of an industry. The EPA ECEL memorandum for Perchloroethylene states that "OSHA's Permissible Exposure Limit (PEL) must undergo both risk assessment and feasibility assessment analyses before selecting a level that will substantially reduce risk under the Occupational Safety and Health Act." Does this imply that EPA does not have to comply with similar constraints?

#### **RESPONSE:**

EPA's mandate under TSCA section 6(b) is to evaluate existing chemicals against a purely risk-based standard, identifying whether there are unreasonable risks of injury to health or the environment without consideration of costs or other non-risk factors, including an unreasonable risk to a potentially exposed or susceptible subpopulation identified as relevant by EPA, under the conditions of use. The Agency must then eliminate any unreasonable risk through regulatory requirements or restrictions outlined in TSCA Section 6(a). In imposing restrictions to eliminate unreasonable risks, TSCA section 6(c)(2) further directs EPA to consider other factors such as reasonably ascertainable economic consequences of the rule and whether technically and economically feasible alternatives that benefit health or the environment compared to a use proposed to be prohibited or restricted will be reasonably available as a substitute. Those considerations help EPA select the best regulatory option among those that effectively eliminate the unreasonable risk, and the Agency takes the obligation to consider these factors seriously.

TSCA section 6(g) provides authority for EPA to issue time-limited exemptions to risk management regulatory requirements in a few instances, including but not limited to instances when the use is a critical or essential use for which no technically or economically feasible safer alternative is available when taking into account hazard and exposure, and instances where compliance with a risk management requirement for a specific condition of use would significantly disrupt the national economy, national security, or critical infrastructure. However, these provisions do not otherwise limit EPA's authority under TSCA to identify an unreasonable risk in risk evaluations, and the requirement to then eliminate the unreasonable risks in a subsequent risk management rule.

Specifically, in the case of the ECELs, EPA has identified the concentration at which individuals would be unlikely to suffer adverse effects if exposed for a working lifetime. This is a risk-based calculation derived from the risk evaluation, incorporating advanced modeling and peer-reviewed methodologies, including accounting for exposures to potentially exposed and susceptible subpopulations, as required by TSCA. In risk management, EPA plans to consider the implementation practicalities to meet an ECEL for relevant conditions of use and will present the analysis regarding the economic consequences of the proposed regulatory requirements, including any requirements to meet an ECEL.

a. If not, ACGIH also does not consider economic or technical feasibility and yet the EPA ECELs are considerably lower than ACGIH TLVs. How does the EPA account for this discrepancy?

#### **RESPONSE:**

There are several reasons why ACGIH TLVs may differ from ECELs. Because many TLVs are several decades old, they may not fully capture either the complete database considered in risk evaluations or more recent advances in modeling and scientific interpretation of toxicological data. ECELs, which EPA considers to represent the best available science, are derived from information in the risk evaluation, which is the result of a rigorous systematic review process that

includes an investigation of the entirety of the reasonably available current literature in order to identify all relevant adverse health effects. Additionally, by using the information from the risk evaluation, ECELs incorporate advanced modeling and peer-reviewed methodologies for determining exposure levels below which unreasonable risk to health would no longer be presented.

6. The Environmental Protection Agency (EPA) must develop risk determinations for each chemical's condition of use by deciding if that chemical presents an unreasonable risk to humans or the environment based on the inherent toxicity and likely exposure. Do you believe the Toxic Substances Control Act reform intended for every chemical substance the EPA reviews to be found to present an unreasonable risk?

## **RESPONSE:**

TSCA directs EPA to "conduct risk evaluations...to determine whether a chemical substance presents an unreasonable risk of injury to health or the environment, without consideration of costs or other nonrisk factors, including an unreasonable risk to a potentially exposed or susceptible subpopulation identified as relevant to the risk evaluation by the Administrator, under the conditions of use." 15 U.S.C. 2605(b)(4)(A). I don't believe Congress expected that EPA would find "unreasonable risk" for every one of the tens of thousands of chemicals in commerce. Neither the law nor our regulations pre-judge the outcome of the risk evaluation process. We expect to follow the law and follow the science in implementing our responsibilities under the statute.

a. How will EPA ensure that real world exposure data from the workplace will be used in lieu of overly conservative default assumptions that may inaccurately characterize the workplace?

#### **RESPONSE:**

Where real world exposure data exists and is made available to the Agency, we do consider that information during the risk evaluation process. There are numerous opportunities during the TSCA process for submission of data to inform EPA's efforts, and we strongly encourage companies and other stakeholders to share relevant information that they may have, as early in the process as possible. We are also committed to doing a better job at characterizing our risk findings. We know, for example, that many companies go above and beyond what they are required to do to protect their workers. In addressing unreasonable risks identified in TSCA risk evaluations, we plan to strive for consistency with OSHA rules and industry best practices wherever possible, leveling the playing field for all companies, while still ensuring that all workers are protected against unreasonable risk no matter where they live or who employs them.

7. In your proposed risk management rule for asbestos, can you please clarify for me if it was EPA's intent to force the removal and replacement of every asbestos gasket within two years?

### **RESPONSE:**

EPA proposed to prohibit the manufacturing, processing, distribution in commerce, and commercial use of asbestos-containing gaskets, including the commercial use of existing asbestos-containing gaskets. Under the proposed rule, this prohibition would take effect two years after the effective date of the final rule for sheet gaskets in chemical production, and 180 days after the effective date of the final rule for other gaskets. EPA did not, however, intend for this rule to force removal of significant numbers of asbestos gaskets before the end of their useful life. In fact, EPA recognizes that there could be unintended consequences of doing so in terms of increased exposures and risks during the removal and subsequent disposal. EPA is reviewing the feedback received during the public comment period from stakeholders on the proposed rule and will consider, based on that feedback, potential improvements to clarify, and amend as necessary, the scope of the rule's requirements.

#### June 24, 2021

The Honorable Chellie Pingree

Chairwoman

Subcommittee on Interior, Environment, and

Related Agencies

House Committee on Appropriations

Washington, D.C. 20515

The Honorable David Joyce

Ranking Member

Subcommittee on Interior, Environment, and

Related Agencies

House Committee on Appropriations

Washington, D.C. 20515

The Honorable Jeff Merkley

Chairman

Subcommittee on Interior, Environment, and

Related Agencies

Senate Committee on Appropriations

Washington, D.C. 20510

The Honorable Lisa Murkowski

Ranking Member

Subcommittee on Interior, Environment, and

Related Agencies

Senate Committee on Appropriations

Washington, D.C. 20510

## **RE: US EPA Safer Choice Program**

Dear Chairwoman Pingree, Chairman Merkley, Ranking Members Joyce and Murkowksi:

We are writing to express our strong support for the Environmental Protection Agency's (EPA) Safer Choice Program and to encourage you to provide funding at a level that allows the program to be fully staffed and resourced.

In addition, we ask you to include the following report language:

The Committee supports the Safer Choice program and directs that the program be funded and operated at least at levels consistent with Fiscal Year 2014, adjusted for inflation.

There is precedent for including supportive language on Safer Choice in your subcommittees' bill. The joint explanatory statement accompanying Division G of your FY21 bill included the following language:

The Committees support the Safer Choice program and direct that the program be funded and operated consistent with prior years.

Similar language also accompanied the FY20 Senate bill. Despite this clear direction from the committee, over the last four years, resources and leadership have been drained from Safer Choice.

For most of its existence, this unique and valuable program was organized within its own branch, staffed with as many as 13 full-time employees, including a branch chief, toxicologists and chemists. In the last quarter of 2020, EPA announced a reorganization of the Office of Chemical Safety and Pollution Prevention (OCSPP) whereby the Safer Choice branch was dissolved and most staff were reassigned to other areas of OCSPP. As a result, the program is now severely under-resourced with approximately four full-time staff. New leadership at EPA has taken steps to restore the program, but the agency faces resource constraints. We urge you to fully restore the Safer Choice Program – a broadly supported, and impactful recognition program that helps drive a market for safer chemicals and products.

Companies across the value chain utilize the Safer Choice brand to advance their individual safer chemical initiatives – from brand owners to retailers to chemical manufacturers. For example, chemical manufacturers have invested in the difficult task of developing safer chemicals now listed on the Safer

Choice's Safer Chemicals Ingredients List (SCIL). Having chemicals on the SCIL allows these manufacturers to offer best-in-class safer chemicals to the market that carry the robust third-party verification of the EPA. Brand owners and product manufacturers have invested in Safer Choice by undertaking the similarly resource-intensive effort to reformulate products using the SCIL to obtain Safer Choice certification. Major retailers specify the Safer Choice label as a way to verifiably meet corporate goals laid out in public-facing chemicals policies.

The Safer Choice Program also provides value to entities outside of the supply chain. Numerous states and municipalities rely on Safer Choice because it is the only third-party program that requires all ingredients to be screened for hazards instead of simply using a restricted substances list. Several state and local governments specify Safer Choice labeled products in their purchasing contracts as well as point to Safer Choice in public education campaigns and outreach. Non-governmental organizations and consumers find significant value in an authoritative government program that can be trusted to vet safer chemicals and products.

We believe that the Safer Choice Program provides a unique space for product innovation while maintaining high standards for health, safety, and functional use. Safe products that work are increasingly important as consumer awareness and concerns grow about the potential harm that many formulated consumer products can pose to their health and the environment.

The signatories to this letter represent a unique and broad group of chemical manufacturers, brand owners, environmental NGOs, states and municipalities. We respectfully urge you to quickly restore the Safer Choice Branch and its staffing to their previous levels so that they may stabilize the program and serve the constituency they have worked hard to build over the last decade.

Sincerely yours,

ABC Compounding Co., Inc. City of San Francisco

Aicello America Corp City of Santa Monica

Alternative Fuels & Chemicals Coalition Clean Control Corporation

American Cleaning Institute Clorox Company

Amway Cole Hardware

BASF Corporation Cradle to Cradle Products Innovation Institute

Belle Aire Creations CRC Industries, Inc.

Berkley Green Defunkify

Beyond Benign DeltaGreen Products, Inc.

Booyah Clean Diamond Chemical

Breast Cancer Prevention Partners Earth Friendly Products, ECOS

California Green Business Network Ecolab, Inc.

Canberra Corporation ECOS

Cascadia Consulting Group Envirocon Technologies Inc (Lemi Shine)

ChemFORWARD Environmental Biotech International

**Environmental Council of the States** 

**Environmental Defense Fund** 

EPA R7

GOJO Industries, Inc.

Green Chemistry & Commerce Council

Green Life Development, Inc.

GreenBlue

Hartz Mountain Corporation

Henkel

HLF Diversified Inc.

Holloway House, Inc.

Household & Commercial Products

Association

**IFF** 

Industrial Chemical Solutions, LLC

inShield Wiper, LLC

ISSA-The Worldwide Association for the

Cleaning Industry

Itaconix Corporation

Jelmar, LLC

Lauren Kuby, Tempe City Council

Levi Strauss & Co

Lighthouse for the Blind

McFadden and Associates, LLC

Michigan Sustainable Business Forum

Minnesota Pollution Control Agency

Momar, Incorporated

National Pollution Prevention Roundtable

National Retail Federation

Native Green

OMI Industries, Inc.

Oregon Association of Clean Water Agencies

Oregon Department of Environmental Quality

Osprey Biotechnics

Pollution Prevention Resource Center

Procter & Gamble

**PROSOCO** 

PurposeBuilt Brands

Reckitt Benckiser LLC

Safer Chemicals Healthy Families
San Benito County Integrated Waste

Management

Sapient Living LLC

Scientific & Regulatory Consultants, Inc.

Sensitive Home

Sozio Fragrances

Sozio, Inc.

Spartan Chemical Company, Inc.

SSB IP Holdings LLC

**State Industrial Products** 

Stepan

Sunshine Makers, Inc.

Sustainable Works - Green Business Program

The Ashkin Group LLC

The Hate Stains Co.

ToxServices LLC

Vi-Jon, LLC

Vinagreen, LLC

West Michigan Sustainable Business Forum

Wexford Labs, Inc.

Whisk Products, Inc.

Women's Voices for the Earth

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ENVIRONMENTAL ENGINEER       13         TOXICOLOGIST       13         Risk Assessment Branch 2         SUPERVISORY TOXICOLOGIST         LEAD BIOLOGIST       14         LEAD BIOLOGIST       14         BIOLOGIST       14         EPIDEMOLOGIST       13         BIOLOGIST       13         BIOLOGIST       13         CHEMICAL ENGINEER       13         ENVIRONMENTAL ENGINEER       13         ENVIRONMENTAL ENGINEER       13         TOXICOLOGIST       13         TOXICOLOGIST       13         CHEMICAL ENGINEER       12         PHYSICAL SCIENTIST       12         Risk Assessment Branch 4	PHYSICAL SCIENTIST	13		
TOXICOLOGIST	PHYSICAL SCIENTIST	13		
Risk Assessment Branch 2	ENVIRONMENTAL ENGINEER	13		
SUPERVISORY TOXICOLOGIST       15         LEAD BIOLOGIST       14         BIOLOGIST       14         EPIDEMOLOGIST       14         BIOLOGIST       13         BIOLOGIST       13         CHEMICAL ENGINEER       13         ENVIRONMENTAL ENGINEER       13         ENVIRONMENTAL ENGINEER       13         TOXICOLOGIST       13         TOXICOLOGIST       13         CHEMICAL ENGINEER       12         PHYSICAL SCIENTIST       12         Risk Assessment Branch 4	TOXICOLOGIST	13		
LEAD BIOLOGIST       14         BIOLOGIST       14         BIOLOGIST       14         EPIDEMOLOGIST       13         BIOLOGIST       13         BIOLOGIST       13         CHEMICAL ENGINEER       13         ENVIRONMENTAL ENGINEER       13         ENVIRONMENTAL ENGINEER       13         TOXICOLOGIST       13         TOXICOLOGIST       13         CHEMICAL ENGINEER       12         PHYSICAL SCIENTIST       12         Risk Assessment Branch 4	Risk Assessm	nent Branch 2		
LEAD BIOLOGIST       14         BIOLOGIST       14         EPIDEMOLOGIST       13         BIOLOGIST       13         CHEMICAL ENGINEER       13         ENVIRONMENTAL ENGINEER       13         ENVIRONMENTAL ENGINEER       13         TOXICOLOGIST       13         TOXICOLOGIST       13         CHEMICAL ENGINEER       12         PHYSICAL SCIENTIST       12         Risk Assessment Branch 4	SUPERVISORY TOXICOLOGIST	15		
BIOLOGIST	LEAD BIOLOGIST	14		
EPIDEMOLOGIST       14         BIOLOGIST       13         BIOLOGIST       13         CHEMICAL ENGINEER       13         ENVIRONMENTAL ENGINEER       13         ENVIRONMENTAL ENGINEER       13         TOXICOLOGIST       13         TOXICOLOGIST       13         CHEMICAL ENGINEER       12         PHYSICAL SCIENTIST       12         Risk Assessment Branch 4	LEAD BIOLOGIST	14		
BIOLOGIST       13         BIOLOGIST       13         CHEMICAL ENGINEER       13         ENVIRONMENTAL ENGINEER       13         ENVIRONMENTAL ENGINEER       13         TOXICOLOGIST       13         TOXICOLOGIST       13         CHEMICAL ENGINEER       12         PHYSICAL SCIENTIST       12         Risk Assessment Branch 4	BIOLOGIST	14		
BIOLOGIST       13         CHEMICAL ENGINEER       13         ENVIRONMENTAL ENGINEER       13         ENVIRONMENTAL ENGINEER       13         TOXICOLOGIST       13         TOXICOLOGIST       13         CHEMICAL ENGINEER       12         PHYSICAL SCIENTIST       12         Risk Assessment Branch 4	EPIDEMOLOGIST	14		
CHEMICAL ENGINEER       13         ENVIRONMENTAL ENGINEER       13         ENVIRONMENTAL ENGINEER       13         TOXICOLOGIST       13         TOXICOLOGIST       13         CHEMICAL ENGINEER       12         PHYSICAL SCIENTIST       12         Risk Assessment Branch 4	BIOLOGIST	13		
ENVIRONMENTAL ENGINEER       13         ENVIRONMENTAL ENGINEER       13         TOXICOLOGIST       13         TOXICOLOGIST       13         CHEMICAL ENGINEER       12         PHYSICAL SCIENTIST       12         Risk Assessment Branch 4	BIOLOGIST	13		
ENVIRONMENTAL ENGINEER         13           TOXICOLOGIST         13           TOXICOLOGIST         13           CHEMICAL ENGINEER         12           PHYSICAL SCIENTIST         12           Risk Assessment Branch 4	CHEMICAL ENGINEER	13		
TOXICOLOGIST         13           TOXICOLOGIST         13           CHEMICAL ENGINEER         12           PHYSICAL SCIENTIST         12           Risk Assessment Branch 4	ENVIRONMENTAL ENGINEER	13		
TOXICOLOGIST 13  CHEMICAL ENGINEER 12  PHYSICAL SCIENTIST 12  Risk Assessment Branch 4	ENVIRONMENTAL ENGINEER	13		
CHEMICAL ENGINEER 12 PHYSICAL SCIENTIST 12 Risk Assessment Branch 4	TOXICOLOGIST	13		
PHYSICAL SCIENTIST 12  Risk Assessment Branch 4	TOXICOLOGIST	13		
Risk Assessment Branch 4	CHEMICAL ENGINEER	12		
	PHYSICAL SCIENTIST	12		
PHYSICAL SCIENTIST 13	Risk Assessment Branch 4			
	PHYSICAL SCIENTIST	13		

LEAD BIOLOGIST	14		
LEAD BIOLOGIST	14		
STUDENT TRAINEE (ENV PROTECTION)	05		
BIOLOGIST	12 14		
TOXICOLOGIST			
ENVIRONMENTAL SCIENTIST	14		
CHEMICAL ENGINEER	13		
LEAD BIOLOGIST	14		
SUPERVISORY BIOLOGIST CHEMICAL ENGINEER	15		
Risk Assessm	13		
SUPERVISORY TOXICOLOGIST	15		
LEAD BIOLOGIST	14		
LEAD BIOLOGIST	14		
TOXICOLOGIST	14		
BIOLOGIST	13		
BIOLOGIST	13		
EPIDEMIOLOGIST	13		
PHYSICAL SCIENTIST	13		
BIOLOGIST	12		
PHYSICAL SCIENTIST	12		
PHYSICAL SCIENTIST	12		
BIOLOGIST	11		
BIOLOGIST	11		
INDUSTRIAL HYGIENIST	11		
Risk Assessm	nent Branch 6		
SUPERVISORY BIOLOGIST	15		
LEAD TOXICOLOGIST	14		
BIOLOGIST	13		
CHEMICAL ENGINEER	13		
PHYSICAL SCIENTIST	13		
PHYSICAL SCIENTIST	13		
PHYSICAL SCIENTIST	13		
TECHNICAL INFORMATION SPECIALIST	13		
TOXICOLOGIST	13		
BIOLOGIST	12		
ENVIRONMENTAL ENGINEER	12		
Existing Chemicals Risl	« Management Division		
Immediate Office			
SUPV ENVIRONMENTAL PROTECTION SPC	15		
ENVIRONMENTAL PROTECTION SPECIALIST	15		
ENVIRONMENTAL PROTECTION SPECIALIST	14		

Risk Management Branch 1			
SUPVY ENVIRON PROTECTION SPEC	15		
LEAD ENVIRONMENTAL PROTECTION SPC	14		
LEAD ENVIRONMENTAL PROTECTION SPC	14		
ATTORNEY-ADVISER	14		
ENVIRONMENTAL PROTECTION SPECIALIST	14		
ENVIRONMENTAL PROTECTION SPECIALIST	13		
ENVIRONMENTAL PROTECTION SPECIALIST	13		
ENVIRONMENTAL PROTECTION SPECIALIST	12		
ENVIRONMENTAL PROTECTION SPECIALIST	12		
ENVIRONMENTAL PROTECTION SPECIALIST	11		
ENVIRONMENTAL PROTECTION SPECIALIST	09		
Risk Manage	ment Branch 2		
SUPV ENVIRONMENTAL PROTECTION SPC	15		
LEAD ENVIRONMENTAL PROTECTION SPC	14		
LEAD ENVIRONMENTAL PROTECTION SPC	14		
ENVIRONMENTAL PROTECTION SPECIALIST	14		
ENVIRONMENTAL PROTECTION SPECIALIST	13		
ENVIRONMENTAL PROTECTION SPECIALIST	13		
ENVIRONMENTAL PROTECTION SPECIALIST	13		
ENVIRONMENTAL PROTECTION SPECIALIST	13		
ENVIRONMENTAL PROTECTION SPECIALIST	13		
ENVIRONMENTAL PROTECTION SPECIALIST	13		
ENVIRONMENTAL PROTECTION SPECIALIST	12		
ENVIRONMENTAL PROTECTION SPECIALIST	11		
ENVIRONMENTAL PROTECTION SPECIALIST	11		
Risk Manage	ment Branch 3		
SUPVY PHYSICAL SCIENTIST	15		
LEAD ENVIRONMENTAL PROTECTION SPC	14		
LEAD PHYSICAL SCIENTIST	14		
ATTORNEY ADVISOR (GENERAL)	14		
ENVIRONMENTAL PROTECTION SPECIALIST	14		
BIOLOGIST	13		
ENVIRONMENTAL PROTECTION SPECIALIST	13		
ENVIRONMENTAL PROTECTION SPECIALIST	13		
PHYSICAL SCIENTIST	13		
ENVIRONMENTAL PROTECTION SPECIALIST	12		
ENVIRONMENTAL PROTECTION SPECIALIST	11		
ENVIRONMENTAL PROTECTION SPECIALIST	11		
	licy Analysis Branch		
SUPERVISORY ECONOMIST	15		
LEAD ECONOMIST	14		
ECONOMIST	15		
ECONOMIST	14		
ECONOMIST	14		
ECONOMIST	13		
ECONOMIST	13		

ECONOMIST	13
ECONOMIST	13
ECONOMIST	13
ECONOMIST	13
ECONOMIST	12
ECONOMIST	12
	emicals Division
	ediate Office
DIRECTOR, NEW CHEMICALS DIVISION	00
ENVIRONMENTAL PROTECTION SPECIALIST	15
TOXICOLOGIST	15
	essment Branch 1
SUPERVISORY BIOLOGIST	15
SUPERVISORY TOXICOLOGIST	15
LEAD ENVIRONMENTAL ENGINEER	14
TOXICOLOGIST	14
BIOLOGIST	13
CHEMICAL ENGINEER	13
CHEMICAL ENGINEER	13
TOXICOLOGIST	13
BIOLOGIST	12
BIOLOGIST	12
Risk Asse	essment Branch 2
SUPVY PHYSICAL SCIENTIST	15
LEAD BIOLOGIST	14
LEAD PHYSICAL SCIENTIST	14
MICROBIOLOGIST	14
TOXICOLOGIST	14
BIOLOGIST	13
BIOLOGIST	13
CHEMICAL ENGINEER	13
CHEMICAL ENGINEER	13
ENVIRONMENTAL ENGINEER	13
MICROBIOLOGIST	13
MICROBIOLOGIST	13
PHYSICAL SCIENTIST	13
TOXICOLOGIST	13
BIOLOGIST	12
Risk Mana	agement Branch 1
SUPERVISORY BIOLOGIST	15
LEAD ENVIRONMENTAL PROTECTION SPC	14
LEAD ENVIRONMENTAL PROTECTION SPC	14
ENVIRONMENTAL PROTECTION SPECIALIST	15
ENVIRONMENTAL PROTECTION SPECIALIST	14
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ENVIRONMENTAL PROTECTION SPECIALIST	13
ENVIRONMENTAL PROTECTION SPECIALIST	13
INDUSTRIAL HYGIENIST	13
ENVIRONMENTAL PROTECTION SPECIALIST	12
Risk Manage	ement Branch 2
SUPVY PHYSICAL SCIENTIST	15
LEAD ENVIRONMENTAL PROTECTION SPC	14
ENVIRONMENTAL PROTECTION SPECIALIST	14
BIOLOGIST	13
BIOLOGIST	13
ENVIRONMENTAL PROTECTION SPECIALIST	12
ENVIRONMENTAL PROTECTION SPECIALIST	12
ENVIRONMENTAL PROTECTION SPECIALIST	12
ENVIRONMENTAL PROTECTION SPECIALIST	09
	emistry Branch
SUPVY CHEMIST	15
LEAD CHEMIST	14
LEAD CHEMIST	14
CHEMIST	14
CHEMIST	13
LIFE SCIENTIST	13
PHYSICAL SCIENTIST	13
Data Gathering a	nd Analysis Division
Immed	ate Office
DIR, DATA GATHERING AND ANALYSIS DIV	00
SUPERVISORY BIOLOGIST	15
BIOLOGIST	15
MANAGEMENT ANALYST	15
Data Colle	ctions Branch
SUPERVISORY BIOLOGIST	15
LEAD BIOLOGIST	14
LEAD PHYSICAL SCIENTIST	14
CHEMIST	15
	1

CHEMICAL ENGINEER	14		
ENVIRONMENTAL PROTECTION SPECIALIST	13		
PROGRAM ANALYST	13		
CHEMIST	12		
BIOLOGIST	11		
ENVIRONMENTAL PROTECTION SPECIALIST	09		
Data Analysis ar	nd Dissemination Branch		
SUPERVISORY LIFE SCIENTIST	15		
LEAD ENVIRONMENTAL PROTECTION SPC	14		
CHEMICAL ENGINEER	14		
ENVIRONMENTAL PROTECTION SPECIALIST	14		
ENVIRONMENTAL PROTECTION SPECIALIST	14		
BIOLOGIST	13		
BIOLOGIST	13		
CHEMIST	13		
ENVIRONMENTAL PROTECTION SPECIALIST	13		
ENVIRONMENTAL PROTECTION SPECIALIST	13		
PROGRAM ANALYST	13		
BIOLOGIST	12		
ENVIRONMENTAL PROTECTION SPECIALIST	12		
Prioritization an	nd Informatics Branch 1		
SUPVY CHEMIST	15		
LEAD BIOLOGIST	14		
CHEMIST	14		
BIOLOGIST	13		
CHEMICAL ENGINEER	13		
EPIDEMOLOGIST	13		
EPIDEMIOLOGIST	13		
CHEMIST	11		
	nd Informatics Branch 2		
SUPVY PHYSICAL SCIENTIST	15		
LEAD BIOLOGIST	14		
LEAD TOXICOLOGIST	14		
BIOLOGIST	13		
BIOLOGIST	13		
BIOLOGIST	13		
CHEMIST	13		
CHEMIST	13		
CHEMIST	13		
BIOLOGIST Project Management	12		
	ent and Operations Division		
Immediate Office			

DIR, PROJECT MGMT AND OPERATIONS DIV	00			
SUPVY PROGRAM ANALYST	15			
PROGRAM SPECIALIST	15			
PROGRAM SPECIALIST	15			
	Management Branch			
SUPV INFO MANAGEMENT SPECIALIST	15			
LEAD IT SPEC (PLCYPLN/DATAMGT)	14			
ENVIRONMENTAL PROTECTION SPECIALIST	13			
ENVIRONMENTAL PROTECTION SPECIALIST	13			
ENVIRONMENTAL PROTECTION SPECIALIST	13			
IT SPEC (CUSTSPT)	13			
IT SPECIALIST (SYSADMIN/CUSTSPT)	13			
IT SPECIALIST (CUSTSPT/PLCYPLN)	13			
PROGRAM ANALYST	13			
ENVIRONMENTAL PROTECTION SPECIALIST	11			
TSCA CBI Policy and	Implementation Branch			
SUPVY INFO MANAGEMENT SPECIALIALIST	15			
LEAD ENVIRONMENTAL PROTECTION SPC	14			
ATTORNEY-ADVISER	14			
ENVIRONMENTAL PROTECTION SPECIALIST	13			
ENVIRONMENTAL PROTECTION SPECIALIST	13			
ENVIRONMENTAL PROTECTION SPECIALIST	11			
ENVIRONMENTAL PROTECTION SPECIALIST	07			
Project and Performan	ce Management Branch			
SUPVY PROJECT MGT SPEC	15			
LEAD PROJECT MANAGEMENT SPECIALIST	14			
ENVIRONMENTAL PROTECTION SPECIALIST	13			
ENVIRONMENTAL PROTECTION SPECIALIST	13			
ENVIRONMENTAL PROTECTION SPECIALIST	13			
IT SPECIALIST (POLICY AND PLANNING)	13			
IT SPECIALIST (POLICY AND PLANNING)	13			
IT SPECIALIST (POLICY AND PLANNING	13			
IT SPECIALIST (POLICY AND PLANNING	12			
Stakeholder Engagement Branch				
SUPVY ENVIRON PROTECTION SPEC	15			
LEAD ENVIRONMENTAL PROTECTION SPC	14			
BIOLOGIST	13			
ENVIRONMENTAL PROTECTION SPECIALIST	13			
ENVIRONMENTAL PROTECTION SPECIALIST	13			
ENVIRONMENTAL PROTECTION SPECIALIST	13			
IT SPEC (INET)	13			
ENVIRONMENTAL PROTECTION SPECIALIST	09			